

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of :  
Horst Georg ZERBE et al. :  
Serial No. NEW : **Attn: APPLICATION BRANCH**  
Filed February 5, 2004 : Attorney Docket No. 2004-0189  
WATER SOLUBLE FILM FOR ORAL  
ADMINISTRATION WITH  
INSTANT WETTABILITY : **THE COMMISSIONER IS AUTHORIZED  
TO CHARGE ANY DEFICIENCY IN THE  
FEE FOR THIS PAPER TO DEPOSIT  
ACCOUNT NO. 23-0975.**  
**(Rule 1.53(b) Continuation of Serial No.  
10/143,962, Filed May 14, 2002)**

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of [X] the references listed on attached form PTO-1449 and/or [] the additional information identified below in paragraph 3. A legible copy of each reference listed on the form PTO-1449 was previously cited by or submitted to the Patent Office in prior parent application Serial No. 08/904,607, Serial No. 09/287,181, Serial No. 09/630,562, Serial No. 09/927,327, and Serial No. 10/143,962.

1a. [X] This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, or

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

**and thus no certification and/or fee is required.**

- 1b. ☐ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

(1) ☐ the certification of paragraph 2 below is provided, **or**

(2) ☐ the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

- 1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

**the certification of paragraph 2 below is provided, and**

**the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.**

2. It is hereby certified

a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or

b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.


3. ☐ Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.

4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
- a. ☒ a full or partial English language translation of record in a prior parent application,
  - b. ☒ a foreign patent office search report (in the English language) of record in a prior parent application,
  - c. ☒ the concise explanation contained in the specification of the present application at pages 2-3,
  - d. ☐ the concise explanation set forth in the attached English language abstract,
  - e. ☐ the concise explanation set forth below or on a separate sheet attached to the reference:
5. ☒ A foreign patent office search report citing one or more of the references is of record in a prior parent application.
6. ☒ Comments:

Applicants note that in the immediate parent application, Serial No. 10/143,962, the Examiner issued a double patenting rejection based on claims of USP 5,948,430 (issued from the first parent application of the present divisional application), which was overcome by filing a Terminal Disclaimer.

Respectfully submitted,

Horst Georg ZERBE et al.

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February 5, 2004

FORM PTO 1449 (modified)

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)  
(Use several sheets if necessary)

Date Submitted to PTO: February 5, 2004

ATTY DOCKET NO.  
2004-0189SERIAL NO.  
NEWAPPLICANT  
Horst Georg ZERBE et al.FILING DATE  
February 5, 2004

GROUP

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,413,792	5/1999	Ninomiya et al.			
	AB	5,492,937	2/1996	Borgentoft et al.			
	AC	5,700,478	12/1997	Biegajski et al.			
	AD	5,472,704	12/1995	Santus et al.			
	AE	5,346,701	9/1994	Heiber et al.			
	AF	5,229,164	7/1993	Pins et al.			
	AG	5,047,244	9/1991	Sanvordeker et al.			
	AH	4,900,552	2/1990	Sanvordeker et al.			
	AI	4,031,200	6/1977	Reif			
	AJ	4,029,758	6/1977	Mlodozieniec et al.			
	AK	4,029,757	6/1977	Mlodozieniec et al.			
	AL	4,876,092	10/1989	Mizobuchi et al.			
	AM	5,462,749	10/1995	Rencher			
	AN	4,713,239	12/1987	Babaian et al.			
	AO	4,579,858	4/1986	Ferno et al.			
	AP	5,446,070	8/1995	Mantelle			
	AQ	5,599,554	2/1997	Majeti			
	AR	5,783,207	7/1998	Stanley et al.			
	AS	5,804,209	9/1998	Ponti et al.			
EXAMINER				DATE CONSIDERED			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of form with next communication to applicant.

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## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO	
	BA	95/18046	7/1995	WIPO				
	BB	91/06270	5/1991	WO				
	BC	0 200 508	10/1991	Europe				
	BD	1 263 312	11/1989	Canada				
	BE	2 449 865	4/1976	Germany				
	BF	3 630 603	3/1988	Germany				
	BG	0 219 762	4/1987	Europe				
	BH	0 452 446	10/1991	Europe				
	BI	0 381 194	8/1990	Europe				
	BJ	24 32 925	1/1976	Germany				
	BK	91/05540	5/1991	WO				
	BL	0 259 749	3/1988	Europe				
	BM	0 781 550	7/1997	Europe				
	BN	0 250 187	12/1987	Europe				
	BO	92/15289	9/1992	WO				

## OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	BP	
	BQ	
	BR	

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*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,626,866	5/1997	Ebert et al.			
	AB	6,221,383 B1	4/2001	Miranda et al.			
	AC						
	AD						
	AE						
	AF						

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO	
	AG	5-236885	9/1993	Japan			X	
	AH	5-41602	6/1993	Japan			X	
	AI							
	AJ							

## OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	AK	F.V. Bruchhausen (ed.): Hagers Handbuch der pharmazeutischen Praxis, vol. 2, 1991, page 849 (in German) & and partial English translation thereof.
	AL	Y.W. Chien, <u>Novel Drug Delivery Systems</u> , New York: Marcel Dekker, Inc., 1992, pages 171-173.
	AM	V.V. Ranade and M.A. Hollinger (ed.): <u>Drug Delivery Systems</u> , Florida: CRC Press, Inc., 1996, pages 62-65.
	AN	J. Anderson, <u>Advances in Drug Delivery Systems</u> , 6, pages 37-38 (1994).
	AO	CAPLUS abstract (1986:193234) & JP 61030516 *abstract*.

EXAMINER

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